JUN 1 8 2002

EXHIBIT A

510(k) Summary of Substantial Equivalence K021019

Substantial Equivalence

In accordance with the requirements of 21 CFR § 807, this summary is formatted with the Agency's final rule ".... 510(k) Summaries and 510(k) Statements..." and can be used to provide equivalence summary to anyone requesting it from the Agency.

Manufacturer	Genzyme Biosurgery A Division of Genzyme Corporation 600 Airport Road Fall River, MA 02720-4740
Contact Person	Mary E. Gray Phone: (508) 677-6512 Fax: (508) 677-6663 e-mail: mgray@genzyme.com
Date Prepared	March 14, 2002

Device Information

Trade Name:	'COTTONY' II, "silky" II POLYDEK® & TEVDEK® II Polyester Nonabsorbable Surgical Suture.
Common Name:	Polyester Nonabsorbable Surgical Sutures.
Classification	Name: Non-Absorbable Poly(ethylene terephthalate) Surgical Sutures

Indications for Use

Polyester Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic orthopedic and neurological procedures.

Device Description

Polyester Nonabsorbable Surgical Suture, USP size 9-0 through 9 available as undyed, dyed D & C Green No. 6 and as a co-braid of the undyed and dyed. The suture is sterile, braided and is provided in a variety of lengths, with or without pledgets, with or without needles and may be supplied in a variety of cut lengths or on ligating reels.

EXHIBIT A

510(k) Summary of Substantial Equivalence Cont.

Substantial Equivalence

The device is similar in intended use, materials, design, and performance characteristics to the currently cleared Polyester Nonabsorbable Surgical Sutures (#K930738).

The determination of substantial equivalence for this device was based on a detailed device description, performance testing and conformance with voluntary performance standards, e.g. ANSI/AAMI/ISO 10993-1 Biological Evaluation of Medical Devices, USP Section XXV - Nonabsorbable Surgical Sutures, and the Guidance Document "Guidance for Surgical Suture 510(k)s" issued on August 10, 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2002

Ms. Mary E. Gray, RAC
Regulatory Affairs Specialist
Genzyme Corporation
600 Airport Road
Fall River, MA 02720-4740

Re: K021019
Trade/Device Name: 'COTTONY' II, "silky" II POLYDEK® & TEVDEK® Polyester Nonabsorable Surgical Suture
Regulation Number: 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: March 25, 2002
Received: March 29, 2002

Dear Ms. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

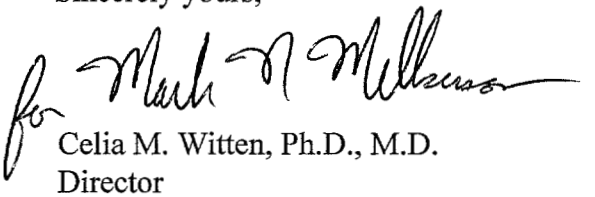
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021019

510(k) Number (if known)

Device Name

'cottony' II DACRON,
"silky" II POLYDEK® & TEVDEK® II
Polyester Nonabsorbable Surgical Suture

Indications for Use

Polyester Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopedic and neurological procedures.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021019

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR § 801.109)

(Optional Format 1-2-96)